UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,990	02/20/2002	Buddy D. Ratner	920010.40001	1736

500 7590 04/26/2004

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
PADGETT, MARIANNE L	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/081,990	Ratner et al
Examiner	**Group Art Unit**
M.L. Padgett	1762

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 8/12/03 & 11/04/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-85 is/are pending in the application.

Of the above claim(s) 1-41, 70, 74 + 82-83 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 42-69, 71-73, 75-81 and 84-85 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). (11/04/02) (8/12/03) ☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

1. Applicant's election without traverse of Group II method claims, with species A being (i) electro spray; and species B, being (i) sugars in Paper No. 8/12/2003 (mail date) is acknowledged.

2. Claims 43, 49-50, 57-65, 81 and 84-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 43, due to the lack of any clear differentiation and the lack of articles showing antecedent basis, it is unclear whether or not the "plasma-treating" of claim 42 is the same as "plasma-treated" of claim 43, i.e., are there now 2 plasma treatments required, or does this dependent claim specify when that of the independent claim is preformed?

In claim 49, as there have never been any "solvents" required to be present, it is not clear when or how what need not be present is separated. As written, this claimed step will be considered optional, unless solvents are positively employed. In claim 50, "dry gas" has an analogous problem to solvents. Furthermore, does this mean that the ionized molecules are wet or made of H_2O or some how related to water or solvents, or what? As written "dry gas" is considered potentially inclusive of any gaseous material, except water vapor.

In claim 51, when, where and of what ions, is the ion current measured? As written any possibilities will be considered, i.e. measurement before, during or after any process step or the overall process; ion current of the plasma or of the ionized molecule source if separate, etc.

In claims 54 and 55, when heating or exposing to UV "activation" (activation of what?) occurs is unstated/unclear, with respect to the process steps of the independent claim. As written, any heating or UV exposure that occurs anytime in the lifetime of the object, i.e., before, during or after the claimed process of 42, will be considered to read on the claims.

In claim 57, "the plasma-treatment" uses inconsistent languages with respect to claim 42 that introduces "plasma-treating". Presumably "the" is referring back to the similar term of the independent claim, however this could be considered speculation on the part of the examiner and a different plasma step than claim 42 may be the requirement, hence clarity of intent should be provided in the claims. Analogously, see claims 58-64 and 84-85. Also, the Markush group of claim 57 is improper, in that 'opening...", "micro-roughening..." and "plasma cleaning..." are all species of "plasma etching...". Also note as written, the "coating..." species may be describing what happens in claim 42's "depositing..." step or may be separate therefrom.

In claims 62-64, it is not stated when these adjustments or changes to various plasma parameters occur, hence as written they may be anytime before or during whatever plasma treatment is being employed. In other words, when setting up the process, adjusting the apparatus parameters to desired levels or outputs reads on these adjusting steps. The claim of changing of the gas feed indicates potential content of multiple different plasmas, hence the question of whether or not the plasma treatment is the same or different from "plasma-treating" is reinforced.

In claim 78, when this limitation occurs, is again not stated, hence may be any time, including taking in and out of the vacuum apparatus, an action that must inherently occur at some time, if the object is ever to be used, etc., any where but in the plasma deposited chamber.

Use of relative terms that lack clear metes and bounds in the claims, or in a definition in the specification or cited relevant prior art, is vague and indefinite. In claim 81, see "long, thin" which requires relative dimensions. In claim 65, see "irregular". Does this mean non-planar, or not smooth i.e. rough or is it in any shape more complex than flat sheet, square, sphere or what?

Note in the above discussion, issues of breath of claims, as well as 112 issues were discussed. While broadness, such as when an action occurs is not necessarily a clarity problem, so generally not included as rejected under 112, 2nd, applicant may wish to consider if these discussed meanings

correspond to their intent, when they consider their claims for the clarity issues. Similarly, in claims 84 and 85, controlled "molecular weight" or "chemical polarity" are specified, however it is noted the mere choice of what polymeric material to use, will have some effect on controlling these features of deposited polymeric substances, hence no more specific meaning or action need necessarily to be considered. Applicant is reminded to cite support for addition to the claim limitations.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application-by-application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 42-43, 52, 54, 57, 60-65, 67, 73 and 84-85 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ratner et al (5,091,204).

In Ratner et all (204), see teachings of plasma treating glass or polymeric lens substrates, for use as interocular lens for implanting in the eye (abstract). The substrate may be first plasma etch with an Ar plasma, then exposed to a plasma of a monomer, such as a fluorocarbon, exemplified by perfluoropropane. System parameters, such as RF power, chamber pressure and reaction time were selected depending on character of monomer used, and varied to control nature of reaction, etc (column 3, lines 1-20; Ex. 1 in column 4 and claims 2-17).

Note controlling powers of plasma inherently exerts control on the kinetic energy of ions of ionized monomer molecules in the plasma. While the type of RF plasmas employed by Ratner et al (204) are relatively low temperature, the plasma process inherently inputs energy into the system, which raises the temperature unless otherwise controlled. As Ratner discloses no such extra temperature control, i.e. cooling, the substrates are inherently heated by the plasmas during processing.

6. Claims (49), 55, 58-59 and 78 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ratner et al (204) as discussed above in Section 5.

In-situ RF plasmas as described in Ratner et al (204), generally produce light radiation as well as ions (Ar and of monomer), electron, etc, to which the substrates are exposed, hence while the PTO cannot measure what wavelength are produced by above Ar & monomer plasmas, Ar in lamps and lasers are known to produce wavelength of light in the 390-444 nm range, i.e. including UV, hence the substrates would have been inherently exposed to UV during the course of the plasma treatments. Alternately, it would have been obvious to one of ordinary skill to use the lens as taught for implantations, so that the

pension (or animal) having the implanted lens, will expose them to UV whenever they are in sunlight or under fluorescent lamps.

While dangling bonds produced by plasma etching are not discussed, plasma etching via Ar+ inherently breaks bonds, thus leaving ends dangling. Alternately, it would have been obvious to one of ordinary skill to supply sufficient energy to the taught Ar-plasma etch to enable activation of the substrate surface by removals of atoms to leave such reactive sites. Also, the deposited monomers may be considered to have substituted for removed/etch polymer surface components.

While Ex. 1 discusses evacuating chamber, plasma processing and letting up to atmospheric pressure with air and Ar, there is no explicit discussion of manipulating the substrate with respect to an air/vacuum/air differentially pumped interface. However, the lens (substrate) is not part of the apparatus, hence must have inherently been manipulated in and out thereof. The evacuation and bringing up to pressure read on differentially pumping. The claim does not specify with respect to what the "interface" exists, so it can just be the chamber. Alternately, it would have been obvious to achieve the evacuation, and letting up to pressure for the apparatus and process of Ratner et al (204) by any conventional means, such as a load-lock chamber or gas flow and evacuation inputs and outputs directly interfaced to the chamber, in order to produce taught results.

As noted above, if there is no solvent to separate from the ionized molecules, claim 49 can be considered optional. Ratner et al ('204) uses no solvent, so this ambiguous claim has been included here.

7. The excerpt from Pappas, ed: UV curing, chapter on light sources, is cited to show wavelengths of light emitted by transitions of excited Ar atoms, thus provide supporting evidence of above assertion of emission of UV light by argon, as sources included discharge lamps, which operate by forming plasmas to emit the light.

8. Claims 42-44, 50-52, 54, 57, 59-67, 73, 81 and 84-85 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ratner (5,002,794).

Claims 49, 55 and 58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ratner et al ('794).

Ratner ('974) is analogous to (204), but employs different polymeric monomers, is taught for a wider variety of substrates, including metals, such as stainless steel as well as various polymers or glass, for a greater variety of uses including lenses, heart valves, catheters (long and thin), etc. Temperature control of the substrate to control the degree of fragmentation of the precursor and explicit discussion of the plasmas as a thermal heat source are present. Also, besides teaching of initial Ar-plasma etching to clean and activate the substrate, the subsequent plasma deposition may be a continuous plasma polymerization reaction or may employ and ON/OFF plasma cycle that may be considered to read on claim 44, since ionized deposits from the previous plasma cycle or that remain and are condensed on the substrate during the OFF period, are subsequently treated by the following plasma period. In Ratner (794), see the abstract; summary; column 5, line 62- column 6, line 62, esp. see lines 39-42 for exemplary substrates; column 7, lines 58-68+; column 8, lines 14-37 and 49-68; column 9, lines 29-36; column 10, lines 9-30 and 38-59; column 12, lines 45-56, esp. lines 48-50 for specific biomed/biotech uses; column 13, lines 1-5; column 14, lines 44-68, for Ar plasma pretreatment/etching and use of liquid processors that have been degassed (i.e., the separated gases may be considered to read on "dry gas"); column 23, lines 4-19, esp. line 7 whereby a current of 1.5 nA Xe^+ is used for a SSIMS analysis beam (note claim 51 does not say when, where for what purpose, etc, the ion current is measure, and this provides an explicit ion current, hence it was measured); column 26, line 1- column 27, line 68+; and claims, esp. 1 and 6.

9. Other references by related inventive entities include Hoffman et al and Horbett et al, which were equivalent to the above Ratner et al references for most of the above rejected claims as present by written. Ratner et al (6,131,580) also plasma deposits a layer, where it is deposited on a sugar layer, but this sugar layer is alternatively spin cast, sol-gel sprayed or dip coated, with no indication that any of these coating techniques for sugar, employed ionized molecules.

10. Claims 42, 52-54 and 60 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schram et al "The Physics of Plasma polymer Deposition".

Schram et al discuss various plasma polymerization deposition techniques, including on page 26 (esp. paragraph bridging pages 26-27), teaching the use of biased substrates to increase the intensity of ion bombardment, i.e. to control the KE of the ions by adjusting the electrostatic potential of the substrate. On page 27, there is also discussion of the use of separate ion sources, but details as to whether the deposition (polymer) reagents are in the plasma or separate ion sources are not given.

11. Claims 42-43, 54-61, 78 and 84-85 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ratner "Ultra thin Films", Salamone, ed.

In this article by Ratner, especially see the first, third, fourth paragraphs on page 8444; Fig. 1 and the full paragraph on page 8445, for teachings of various plasma treatments and depositions, including plasma etching to pretreat/clean, followed by plasma polymerization deposition. Note explicit teachings of the plasma producing UV radiation on page 8444.

12. Claims 42-43,45-48, 51-65, 67-69, 71-73, 75-81 and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galin et al (5,944,753), in view of Winterton et al (6,451,871 B1) plus Buschor (4,993,645), or Chabrecek et al (6,589,655 B2) or Pui et al (2003/0143315 A1 or 2002/007869 A1), or Morozov et al (Anal. Chem. Article) .

In Galin et al, see the Abstract; column 2, lines 37-45; column 3, esp. lines 45-61; column 4, lines 15-39 and 50-58; column 5, lines 26-48; column 6, lines 6-33 and 65- column 8, line 9, esp. column 7, line 15, 29-31 and 41-52 for plasma gas, and lines 53-60 for the option of spray coating a solution or dispersion on the substrate surface; and Ex. 3 in column 9 for plasma pretreatment followed by coating with solution. Galin et al may plasma pretreat polymeric substrates, such as implants, with gases such as O_2, air, or Ar, then spray coat with solutions of sulfated polysaccharides, such as sulfated hyaluronic acid. Galin et al differs from the present claims, by not discussing their sprayed coating material as being or

including ionized molecules, as they only generally refer to the use of spraying, providing no details thereof.

All the secondary references provide for use of spraying techniques for coating biomedical devices, such as lenses using spraying techniques as claimed, variously called electrospraying or electrostatic spraying. In Winterton et al, see the abstract; column 1, lines 13-20; column 3, lines 1-21 and 54- column 4, lines 15, 25-30 and 44-51; column 5, line 10-20 and lines 40-44 which teach electrostatic spraying and incorporate Buschor (4,993,645) by reference to provide details of the spraying device and column 5, line 60- column 10 for discussion of polymeric solutions to use for coating. The examiner takes notice that polysaccharides, which are sugars are polymeric, hence applicable to Winterton et al's technique. In Chabrecek et al, see the abstract, column 3, lines 18-37 and 55-60 and column 8, lines 10-20. In Pui et al (2003), see the abstract Figures 1-16; [0002], [0012-0016+], [0061-0064] includes coating with heparin, a polysaccharide on column 8 of [0064]; or for Pui et al (2002), see abstract; Figures; [0001-0002]; [0009-0010]; [0035-0039]; [0046]; [0056-0057]+, for electro spraying of biomedical material or medicants onto medical devices or to produce coatings thereof. In Morozov et al, see the introduction paragraph for electrospray of solutions including polysaccharides, and the following paragraph for suggestion of use on biodevices; the experimental section on page 1416 for suggestion of specific sugars, Fig. 1 (a), (b) and (c) plus Fig. 2 and discussion thereof for various useful electrospray structures as claimed and the overall apparatus; page 1417 "Effect of Carbohydrates" and page 1419 for further discussion of sugars, and the first column of page 1419 for discussion of current values (measured).

It would have been obvious to one of ordinary skill in the art, to employ any of the "electro-spray" techniques of the secondary references in the process of Galin et al, as the primary reference suggests spraying and the secondary references all spray solutions for purposes analogous to Galvin et al, and provide for use of materials either overlapping or of similar scope as desired in Galin et al, thus

showing the expected effectiveness of these electro- or electrostatic spray techniques when employed for the generic spray teaching of Galin et al.

Note other differences not explicitly discussed in Galin, but discussed as obvious or inherent in above rejections are also applicable here (i.e. heating, UV, etc).

13. Claims 42-43, 45-48, 51-69, 71-73, 75-81 and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostettler et al (5,849,368), in view of Morozov et al; or Pui et al (either), or Chabrecek et al, or Winterton et al plus Buschor.

Hostettler et al has teachings similar to Galin et al, but teaches treatments for a wider variety or more generic medical devices, including metal substrates, such as stainless steel, and may employ 2 consecutive plasma treatments, such as O-containing plasma O_2, air, O_2/Ar followed by N-containing (NH_3), then deposition of hydrogel polymers, which may include polysaccharides, such as hyaluronic acid by spraying or dipping. See the abstract; column 9, lines 49- column 10, line 40; column 11, line 14-column 12, line 13 and 55-67; column 14, lines 13-68+; column 17, lines 1-67+; column 24, lines 45-67+; and column 27, lines 1-54, esp. lines 12; and Ex. 3 on columns 35-37.

As in Galin et al, Hostettler et al, only generally teach spraying, and the combination with the secondary references and motivation thereof is the same as discussed in section 12 above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck, can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained

from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padgett/DH

4/19/04

4/21/04

MARIANNE PADGETT
PRIMARY EXAMINER